

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (currently amended) A crystalline form of gatifloxacin characterized by an x-ray diffraction diagram consisting essentially of a major reflection at about $17.2^\circ \pm 0.2^\circ 2\theta$.

2. (original) The crystalline form of gatifloxacin of claim 1 having an x-ray diffraction diagram substantially as shown in Figure 1.

3. (currently amended) A method of making the crystalline gatifloxacin of claim 1 comprising the steps of:

a) providing, at a temperature of at least about 70°C , a solution of gatifloxacin in a solvent consisting essentially of a mixture of methanol and water, wherein the water is present in the mixture in an amount of volume percent water is about 5 vol-% to about 15 vol-% relative to the methanol,

b) cooling the solution to obtain a suspension,

c) isolating a the solid from the suspension, and

d) drying the isolated recovered solid at a temperature of about 40° C to about 70° C to obtain the crystalline form of gatifloxacin.

4. (original) The method of claim 3 wherein the solution is cooled to ambient temperature and thereafter to a temperature of about 0° C to about 10° C .

5. (currently amended) The method of claim 3 wherein the volume percent water is present in the mixture in an amount of in the solvent is about 10 vol-% relative to the methanol.

6. (currently amended) The method of claim 3 wherein the isolated recovered solid is dried at a temperature of about 55° C .

7. (currently amended) A crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 8.8° , 14.1° , 17.6° , 18.2° , 22.0° , and $22.6^\circ \pm 0.2^\circ 2\theta$.

8. (original) The crystalline form of gatifloxacin of claim 7 having an x-ray diffraction diagram substantially as shown in Figure 2.

9. (currently amended) A method of making the crystalline form of gatifloxacin of claim 8, comprising the steps of:

a) slurring gatifloxacin in ethanol, wherein the gatifloxacin slurred is selected from ~~form T1RP, T1, and mixtures of these~~

i) a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 12.5°, 20.0°, 20.9°, 22.2°, 24.5°, 25.1°, and 28.0° ± 0.2° 2θ,

ii) a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 7.4°, 8.9°, 9.6°, 11.4°, 12.2°, 12.9°, 14.1°, 16.7°, 21.2°, 21.8°, 24.1°, and 26.0° ± 0.2° 2θ, and

iii) mixtures of i) and ii),

b) isolating ~~the~~ a solid from the slurry, and

c) drying the isolated solid at ambient temperature and pressure to obtain the crystalline form of gatifloxacin of claim 8.

10. (currently amended) A crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 11.1°, 11.7°, 12.5° and 23.0° ± 0.2° θ .

11. (original) The crystalline form of gatifloxacin of claim 10 having an x-ray diffraction diagram substantially as shown in Figure 3.

12. (currently amended) A method of making the crystalline form of gatifloxacin of claim 10 comprising the steps of:

a) providing, at a temperature of at least about 75° C, a solution of gatifloxacin in a solvent consisting essentially of a mixture of ethanol and water, wherein the ethanol is present in the mixture in an amount of volume percent ethanol in the mixture is at least about 95 vol-% relative to the water,

b) cooling the solution to obtain whereby a suspension is obtained, and

c) isolating the crystalline form of gatifloxacin from the suspension.

13. (original) The method of claim 12 wherein the solution is cooled to ambient temperature and thereafter to a temperature of about 0° C to about 10°C.

14. (currently amended) The method of claim 12 wherein the ~~volume percent~~ water is present in the mixture in an amount of in the solvent is about 1 vol-% relative to the ethanol.

15. (currently amended) A crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 6.8°, 7.1°, 11.1°, 15.5°, and 17.4° ± 0.2° 2θ.

16. (currently amended) The crystalline form of gatifloxacin of claim 15 having an x-ray diffraction diagram substantially essentially as shown in Figure 4.

17. (currently amended) A method of making the crystalline form of gatifloxacin of claim 15 comprising the steps of:

a) providing, at reflux, a solution of gatifloxacin in a solvent consisting essentially of a mixture of acetonitrile and water, wherein the water is present in the mixture in an amount of volume percent water in the mixture is about 2 vol-% relative to the acetonitrile,

b) cooling the solution to obtain whereby a suspension is obtained,

c) isolating a the solid from the suspension, and

d) drying the isolated solid at about 50° C and a pressure of about 10 to about 400 mm Hg to obtain the crystalline form of gatifloxacin.

18. (previously presented) The method of claim 17, wherein the solution is cooled to ambient temperature and thereafter to a temperature of about 0° C to about 10°C.

19. (currently amended) A crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 9.3°, 11.0°, 12.0°, 14.5°, 18.6° and 21.2° ± 0.2° 2θ.

20. (canceled)

21. (original) The crystalline form of gatifloxacin of claim 20 having an x-ray diffraction diagram substantially as shown in Figure 5.

22. (currently amended) A method of making the crystalline form of gatifloxacin of claim 19 comprising the steps of:

- a) crystallizing gatifloxacin from acetonitrile,
- b) isolating the crystalline gatifloxacin ~~crystallized from acetonitrile~~,
- c) slurring the isolated crystalline gatifloxacin ~~so isolated~~ in a lower alkanol having 1 to 4 carbon atoms for ~~a slurry time of~~ at least about 2 hours, and
- d) isolating the crystalline form of gatifloxacin of claim 19 from the slurry.

23. (original) The method of claim 22 wherein the lower alkanol is ethanol.

24. (currently amended) A crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 7.4°, 8.9°, 9.6°, 11.4°, 12.2°, 12.9°, 14.1°, 16.7°, 21.2°, 21.8°, 24.1°, and 26.0° ± 0.2° 2θ.

25. (original) The crystalline form of gatifloxacin of claim 24 having an x-ray diffraction diagram substantially essentially as shown in Figure 6.

26. (currently amended) A method of making the crystalline form of gatifloxacin of claim 24 comprising the steps of:

- a) crystallizing gatifloxacin from acetonitrile,
- b) isolating the crystalline gatifloxacin ~~crystallized from acetonitrile~~,
- c) slurring the isolated crystalline gatifloxacin ~~so isolated~~ in ethanol for ~~a slurry time of less than~~ about 2 hours ~~or less~~, and
- d) isolating the crystalline form of gatifloxacin of claim 24 from the slurry ~~form T1~~.

27. (currently amended) A method of making gatifloxacin sesquihydrate comprising the step of maintaining a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 11.1°, 11.7°, 12.5° and 23.0° ± 0.2° 2θ ~~gatifloxacin form P~~ at ambient temperature for a time sufficient to effect conversion to the sesquihydrate.

28. (currently amended) The method of claim 27 wherein the crystalline form of gatifloxacin is maintained for ~~maintaining is for a time of~~ about one month.

29. (currently amended) A method of making a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 13.5°, 19.6°, 20.4°, 23.6°, 25.8°, and 28.5° ± 0.2° 2θ gatifloxacin form omega comprising the step of drying gatifloxacin form K at about 50° C and a pressure of about 10 mm Hg.

30. (currently amended) The method of claim 29 wherein the gatifloxacin form K is dried ~~dry~~ ~~is for a time of~~ about 24 hours.

31. (currently amended) A method of making a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 6.7°, 11.3°, 13.8°, and 16.4° ± 0.2° 2θ gatifloxacin crystalline form J comprising the step of drying gatifloxacin form K at about 50° C and atmospheric pressure.

32. (currently amended) The method of claim 31 wherein the gatifloxacin form K is dried ~~dry~~ ~~is for a time of~~ about 12 to about 18 hours.

33. (currently amended) A method of making a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 13.5°, 19.6°, 20.4°, 23.6°, 25.8°, and 28.5° ± 0.2° 2θ gatifloxacin form omega comprising the step of maintaining a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram consisting essentially of a major reflection at about 17.2° ± 0.2° 2θ ~~form L~~ at ambient temperature for a time sufficient to effect conversion to the crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 13.5°, 19.6°, 20.4°, 23.6°, 25.8°, and 28.5° ± 0.2° 2θ form omega.

34. (currently amended) The method of claim 33 wherein the crystalline form of gatifloxacin characterized by an x-ray diffraction diagram consisting essentially of a major reflection at about 17.2° ± 0.2° 2θ is maintained ~~is for a time of~~ about 2 months.

35. (currently amended) A method of making gatifloxacin hemihydrate comprising the step of maintaining a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 8.8°, 14.1°, 17.6°, 18.2°, 22.0°, and 22.6° ± 0.2° 2θ gatifloxacin form M at room temperature for a time sufficient to effect conversion to the hemihydrate.

36. (currently amended) A method of making the crystalline form of gatifloxacin of claim 24 gatifloxacin form T1 comprising the step of heating a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 11.1°, 11.7°, 12.5° and 23.0° ± 0.2° 2θ gatifloxacin form P at 50°C.

37. (currently amended) A pharmaceutical composition comprising at least one pharmaceutically acceptable excipient and at least one of gatifloxacin forms L, M, P, Q, S, and T1.

i) a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram consisting essentially of a major reflection at about 17.2° ± 0.2° 2θ,

ii) a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 8.8°, 14.1°, 17.6°, 18.2°, 22.0°, and 22.6° ± 0.2° 2θ,

iii) a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 11.1°, 11.7°, 12.5° and 23.0° ± 0.2° 2θ,

iv) a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 6.8°, 7.1°, 11.1°, 15.5°, and 17.4° ± 0.2° 2θ,

v) a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 9.3°, 11.0°, 12.0°, 14.5°, 18.6° and 21.2° ± 0.2° 2θ, or

vi) a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 7.4°, 8.9°, 9.6°, 11.4°, 12.2°, 12.9°, 14.1°, 16.7°, 21.2°, 21.8°, 24.1°, and 26.0° ± 0.2° 2θ.